

REMARKS

Allowable Claims

As indicated on page 4 of the Office Action, claims 78, 79, 81, 83, 93, 103 and 104 have been objected to, but have been indicated as allowable if rewritten in independent form. To that end, the Applicants have rewritten claims 78, 79, 81, 83 and 93 in independent form and allowance of the same is respectfully requested. Claim 80 depends from rewritten independent claim 79 and is also submitted to be in condition for allowance.

Claim Rejections – 35 U.S.C. §102

Claims 63-77, 80, 82, 84-92, 94-102, 105 and 106 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,048,762 to Sander et al. (hereafter “the ‘762 patent”). The ‘762 patent is the only reference that has been asserted against the pending claims.

Declaration of Prior Invention in the United States Under 37 C.F.R. §1.131

The ‘762 patent was filed on August 20, 2001 as a national stage application stemming from International PCT Application Serial No. PCT/US98/17769 filed on August 27, 1998 (hereafter “the ‘769 PCT application”), which in turn purports to claim priority as a continuation-in-part of U.S. Patent Application Serial No. 08/920,630 filed on August 27, 1997 (hereafter “the ‘630 parent application”).

The subject application is a divisional of U.S. Patent Application Serial No. 09/698,623 filed on October 27, 2000 (now U.S. Patent No. 6,610,065), which is a divisional of U.S. Patent Application Serial No. 09/181,353 filed on October 28, 1998 (now U.S. Patent No. 6,174,311). Accordingly, the subject application has an effective priority date of October 28, 1998. Accordingly, absent the purported priority claim, the ‘762 patent does not constitute prior art to the subject application.

Additionally, the Applicants submit herewith a Declaration of Prior Invention under 37 C.F.R. §1.131 to remove the ‘769 PCT application as prior art to the subject application, which as indicated above was filed on August 27, 1998. The Declaration has been signed by each of the inventors and indicates that on a date prior to August 27, 1998, the Invention was conceived

of and reduced to practice in the United States. To evidence conception and reduction to practice of the Invention, attached to the Declaration is an Invention Disclosure including drawings and a description of the Invention which correspond to the subject matter disclosed and claimed in the subject patent application. The dates listed on the Invention Disclosure have been blacked out, as well as dimensional data associated with the Invention. However, the joint inventors have declared that the "Date of Conception" and the "Date Constructed" occurred prior to August 27, 1998. The Declaration also indicates that on a date prior to August 27, 1998 and shortly after the Invention was reduced to practice, the Invention was tested in the United States. The joint inventors have further declared that the "Date First Tested" listed on the Invention Disclosure occurred prior to August 27, 1998. Following construction and testing of the Invention, the Invention Disclosure was forwarded to the law firm of Woodard, Emhardt, Naughton, Moriarity & McNett for preparation of a patent application. A patent application disclosing and claiming the Invention was filed with the U.S. Patent and Trademark Office on October 28, 1998. (U.S. Patent Application Serial No. 09/181,353; issued as U.S. Patent No. 6,174,311). The subject patent application claims priority to the parent patent application filed on October 28, 1998.

The Applicant submits that the attached Declaration is effective to remove the '769 PCT application as prior art to the subject application. However, the Applicant reserves the right to refute the claim rejections set forth in the Office Action should the Declaration for any reason be deemed ineffective to remove the '769 PCT application as prior art.

Rejection of Claims under 35 U.S.C. §102(e)

The '762 patent is a national stage application stemming from the '769 PCT application, which in turn purports to claim priority to the '630 parent application as a continuation-in-part application. As indicated above, absent the purported priority claim, the '762 patent does not constitute prior art to the subject application. As also indicated above, the '769 PCT application has been removed as prior art to the subject application via the filing of the Declaration of Prior Invention. Accordingly, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter specifically disclosed in the '630 parent application. A courtesy copy of the as-filed '630 parent application is attached hereto.

The Applicants note that the subject matter disclosed in the '630 parent application does not include all of the subject matter disclosed in the '762 patent. Specifically, the '630 parent application does not include Figures 8D-8G and 9-17 and the corresponding portions of the written description, as present in the '762 patent. Accordingly, the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description of the '762 patent does not constitute prior art to the subject application. Specifically, the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description were added to the '769 PCT application, which as indicated above has been removed as prior art to the subject application via the filing of the Declaration of Prior Invention. As a result, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter disclosed in the '630 parent application, which disclosure is limited to Figures 1-7 and 8A-8C and the corresponding portions of the written description. However, the Applicant reserves the right to challenge the subject matter disclosed in the '630 parent application as constituting prior art to the subject application.

Independent Claim 63

Independent claim 63 has been amended to more clearly define the present invention. Specifically, independent claim 63 now recites, among other elements and features, an elongate bone portion having a generally rectangular cross-section transverse to the longitudinal axis, a first end portion and an opposite second end portion, first and second bone engaging surfaces, and a first sidewall extending between the first and second bone engaging surfaces and comprising "a concave surface extending axially between said first and second end portions".

With regard to the implant 800 illustrated in Figure 8A of the '630 parent application, neither of the implant portions 801A, 801B includes a first sidewall extending between first and second bone engaging surfaces and comprising a concave surface extending between opposite first and second end portions of the implant. Indeed, the only convex surface defined by a sidewall of the implant portions 801A, 801B is located entirely at the far end of the implant 800, and clearly does not extend axially between opposite first and second end portions of the implant, as recited in independent claim 63. Additionally, each of the surfaces defined by the sidewall of the implant portion 801A, 801B adjacent the near end of the implant 800 are planar,

and do not in any way have a concave configuration.

For at least the reasons set forth above, the Applicants submit that independent claim 63, as amended, is patentable over the subject matter disclosed in the '630 parent application. Accordingly, withdrawal of the rejection of independent claim 63 and allowance of the same are respectfully requested.

Each of the claims 64-71, 73-77, 89-92 and 94 depends either directly or indirectly from independent base claim 63 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent claim 63. Additionally, further reasons support the patentability of the claims depending from independent claim 63.

For example, claim 66 has been amended to recite that the implant further comprises a second sidewall having a convex portion extending axially between the first and second end portions. However, the only convex portion defined by the portions 801A, 801B of the implant 800 is located entirely at the far end of the implant 800, and clearly does not extend axially between opposite first and second end portions of the implant. As indicated above, each of the surfaces defined by the sidewall of the implant portions 801A, 801B adjacent the near end of the implant 800 are planar, and do not in any way have a convex configuration.

Claim 69 recites that first bone engaging surface is substantially crescent shaped, and claim 90 recites that the elongate bone portion has a generally crescent shaped cross-section in a plane including the longitudinal axis. However, the implant portions 801A, 801B each have a J-shaped configuration including a planar sidewall, a first end portion having a hook-shaped configuration, and an opposite second end portion including a planar flange extending perpendicularly from the planar sidewall. The Applicants submit that the J-shaped configuration of the implant portions 801A, 801B could not reasonably be construed as being substantially crescent shaped.

Claim 70 recites that "at least one of the first and second bone engaging surfaces includes ridges or teeth." However, neither of the implant portions 801A, 801B includes ridges or teeth. To the contrary, the bone engaging surfaces defined by the implant portions 801A, 801B are flat and smooth, and are devoid of any ridges or teeth.

Claim 75 recites that the first sidewall comprises a first substantially planar surface adjacent the first end portion of the implant and a second substantially planar surface adjacent the second end portion of the implant, with “said concave surface extending between said first and second substantially planar surfaces”. These features are clearly not found in either of the implant portions 800A, 800B of the implant 800.

Claim 76 recites a first endwall positioned between the first and second bone engaging surfaces and adapted to engage an implant holder, and claim 77 further recites that the first endwall comprises a recess or projection to engage the implant holder. As shown in Figures 8A-8B, the implant 800 fails to disclose any element or feature adapted to engage an implant holder, much less a recess or projection.

Rewritten Independent Claim 72

Claim 72 originally depended from independent claim 63, but has been rewritten in independent form and recites, among other elements and features, an elongate bone portion having a generally rectangular cross-section transverse to the longitudinal axis, first and second bone engaging surfaces, and a first sidewall extending between the first and second bone engaging surfaces and comprising a concave surface, and “wherein the first bone engaging surface and the second bone engaging surface are separated by a first height adjacent to a first end and by a second height adjacent to an opposite, second end, wherein said first height is greater than the second height”.

With regard to the implant 800 illustrated in Figure 8A of the ‘630 parent application, the portions 801A, 801B of the implant 800 do not include first and second bone engaging surfaces that are separated by a first height adjacent a first end of the implant and by a second height adjacent an opposite second end of the implant, wherein the first height is greater than the second height. To the contrary, the upper and lower bone engaging surfaces defined by the implant portions 801A, 801B are parallel to one another and define a constant and uniform height along the length of the implant 800. Although the implant embodiment illustrated in Figure 8E of the ‘762 patent appears to define a varying implant height, as indicated above, the implant embodiment disclosed in Figures 8D-8G of the ‘762 patent does not constitute prior art to the subject application. For at least the reasons set forth above, the Applicants submit that rewritten

independent claim 72 is patentable over the subject matter disclosed in the ‘630 parent application. Accordingly, withdrawal of the rejection of independent claim 72 and allowance of the same are respectfully requested.

Independent Claim 82

Independent claim 82 has been amended to more clearly define the present invention. Independent claim 82 now recites, among other elements and features, an elongate bone portion defining a length, a first sidewall comprising a concave surface extending along the length, a second opposite sidewall comprising a convex surface extending along the length and arranged generally parallel to the concave surface, and first and second bone engaging surfaces, wherein at least one of the first or second bone engaging surfaces comprises ridges or teeth.

With regard to the implant 800 illustrated in Figure 8A of the ‘630 parent application, the portions 801A, 801B of the implant 800 do not include a first sidewall comprising a concave surface extending along the length of the implant and a second opposite sidewall comprising a convex surface extending along the length of the implant and arranged generally parallel to the concave surface. Indeed, the only concave and convex surfaces defined by a sidewall of the implant portions 801A, 801B are located entirely at the far end of the implant 800. The concave and convex surfaces do not extend along the length of the implant, but instead extend along a width of the implant and are entirely confined to the far end of the implant 800. Furthermore, neither of the upper and lower bone engaging surfaces defined by the implant portions 801A, 801B include ridges or teeth. To the contrary, the upper and lower bone engaging surfaces defined by the implant portions 801A, 801B are flat and smooth, and are devoid of any ridges or teeth.

For at least the reasons set forth above, the Applicants submit that independent claim 82, as amended, is patentable over the subject matter disclosed in the ‘630 parent application. Accordingly, withdrawal of the rejection of independent claim 82 and allowance of the same are respectfully requested.

Independent Claim 84

Independent claim 84 has been amended to more clearly define the present invention. Specifically, independent claim 84 now recites, among other elements and features, a pair of spinal implants each comprising an elongate bone portion having a generally rectangular cross-section transverse to the longitudinal axis, a first end portion and an opposite second end portion, first and second bone engaging surfaces, and a first sidewall extending between the first and second bone engaging surfaces and “comprising a concave portion extending axially between said first and second end portions”.

With regard to the implant 800 illustrated in Figure 8A of the ‘630 parent application, the portions 801A, 801B of the implant 800 do not include a first sidewall extending between first and second bone engaging surfaces and comprising a concave surface extending between opposite first and second end portions of the implant. Indeed, the only convex surface defined by a sidewall of the implant portions 801A, 801B is located entirely at the far end of the implant 800, and clearly does not extend axially between opposite first and second end portions of the implant, as recited in independent claim 84. Additionally, each of the surfaces defined by the sidewall of the implant portion 801A, 801B adjacent the near end of the implant 800 are planar, and do not in any way have a concave configuration.

For at least the reasons set forth above, the Applicants submit that independent claim 84, as amended, is patentable over the subject matter disclosed in the ‘630 parent application. Accordingly, withdrawal of the rejection of independent claim 84 and allowance of the same are respectfully requested.

Each of the claims 85-88 depends either directly or indirectly from independent base claim 84, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent claim 84. Additionally, further reasons support the patentability of the claims depending from independent claim 84. For example, claim 86 recites “wherein the implants are positioned to lie at an angle oblique to each other.” However, as illustrated in Figure 8A of the ‘630 parent application, the implant portions 801A, 801B are positioned next to one another in a parallel arrangement, and are not positioned to lie at an oblique angle relative to one another.

Independent Claim 95

Independent claim 95 has been amended to more clearly define the present invention. Specifically, independent claim 95 now recites, among other elements and features, an implant formed of bone and comprising “a first end portion having a tool engaging recess” and an opposite second end portion, a first bone engaging surface and an opposite second bone engaging surface, a first side wall having a cavity disposed between the first end portion and the second end portion, with “said cavity defined by a concave surface extending axially between the first end portion and the second end portion”.

As an initial matter, neither of the implant portions 801A, 801B of the implant 800 illustrated in Figure 8A of the ‘630 parent application include a first end portion “having a tool engaging recess”. Indeed, neither end of the implant portions 801A, 801B defines any type of recess configured to engage a tool. Additionally, neither of the implant portions 801A, 801B includes a side wall having a cavity defined by a concave surface extending axially between first and second end portions of the implant. Indeed, the only convex surface defined by a sidewall of the implant portions 801A, 801B is located entirely at the far end of the implant 800, and clearly does not extend axially between opposite first and second end portions of the implant, as recited in independent claim 95. Additionally, each of the surfaces defined by the sidewall of the implant portion 801A, 801B adjacent the near end of the implant 800 are planar, and do not in any way have a concave configuration.

For at least the reasons set forth above, the Applicants submit that independent claim 95, as amended, is patentable over the subject matter disclosed in the ‘630 parent application. Accordingly, withdrawal of the rejection of independent claim 95 and allowance of the same are respectfully requested.

Each of the claims 96-100, 103 and 104 depends either directly or indirectly from independent base claim 95 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent claim 95. Additionally, further reasons support the patentability of the claims depending from independent claim 95.

For example, claim 99 recites that “the first bone engaging surface and the second bone engaging surface include ridges or teeth.” However, neither of the implant portions

801A, 801B includes ridges or teeth. To the contrary, the bone engaging surfaces defined by the implant portions 801A, 801B are flat and smooth, and are devoid of any ridges or teeth. Furthermore, claim 100 recites that “the tool engaging recess comprises an opening to engage an implant holder.” However, as indicated above with regard to independent base claim 95, neither end of the implant portions 801A, 801B defines any type of recess or opening configured to engage a tool.

Additionally, claims 103 and 104 have been amended to depend from independent base claim 95, and have already been indicated on page 4 of the Office Action as reciting patentable subject matter.

Rewritten Independent Claim 101

Claim 101 originally depended from independent claim 95, but has been rewritten in independent form and has been amended to recite, among other elements and features, an implant formed of bone and comprising a first end and an opposite second end, a first bone engaging surface and an opposite second bone engaging surface, first and second side walls, and “wherein the first bone engaging surface and the second bone engaging surface are separated by a first height adjacent to the first end and by a second height adjacent to the second end, wherein said first height is less than the second height.”

However, as indicated above with regard to rewritten independent claim 72, the implant 800 illustrated in Figure 8A of the ‘630 parent application includes implant portions 801A, 801B having upper and lower bone engaging surfaces that are parallel to one another so as to define a constant and uniform height along the length of the implant 800. Although the implant embodiment illustrated in Figure 8E of the ‘762 patent appears to define a varying height, as indicated above, the implant embodiment disclosed in Figures 8D-8G of the ‘762 patent does not constitute prior art to the subject application. For at least the reasons set forth above, the Applicants submit that rewritten independent claim 101 is patentable over the subject matter disclosed in the ‘630 parent application. Accordingly, withdrawal of the rejection of independent claim 101 and allowance of the same are respectfully requested.

Each of the claims 102, 105 and 106 depends from independent base claim 101 and are submitted to be patentable for at least the reasons set forth above in support of the patentability

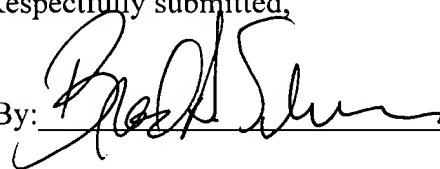
of independent claim 101. Additionally, further reasons support the patentability of the claims depending from independent claim 101. For example, claim 102 recites “wherein the first bone engaging surface and the second bone engaging surface include ridges or teeth”. However, neither of the implant portions 801A, 801B includes ridges or teeth. To the contrary, the bone engaging surfaces defined by the implant portions 801A, 801B are flat and smooth, and are devoid of any ridges or teeth.

CONCLUSION

The Applicant respectfully requests entry of this Amendment and consideration and allowance of the subject application including pending claims 63-106. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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